Prevention of the stapler line leak after laparoscopic sleeve gastrectomy in patients with morbid obesity

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Obesity has become a global pandemic, leading to increased morbidity and mortality among patients, both young and old. Bariatric surgery is the most effective method for treating pathological obesity. Laparoscopic sleeve gastrectomy has become the most popular bariatric procedure worldwide.

However, staple line leak is the most dreaded postoperative complication following laparoscopic sleeve gastrectomy. In order to reduce the incidence of this complication, most surgeons prefer to reinforce the staple line. However, there is no compelling evidence to suggest that peritonealization of the staple line or the use of coated stapler cartridges during laparoscopic sleeve gastrectomy reduces the risk of leakage. Therefore, we conducted a retrospective analysis to assess the impact of coated stapler cartridges on preventing staple line leaks.

The aim of the study. To evaluate the effect of using stapler with coating on preventing staple line leaks during laparoscopic sleeve gastrectomy in patients with morbid obesity.

Materials and methods. This was a retrospective analysis of 45 patients who underwent laparoscopic sleeve gastrectomy using endostapler from Medtronic (Endo GIA™) without additional reinforcement (Group I) and 46 patients who underwent a similar procedure using endostapler from Medtronic (Endo GIA™) stapler with coating (Group II). Both patient groups were homogeneous in terms of demographic characteristics. We compared the duration of surgery, intraoperative blood loss, length of hospital stay, and the incidence of staple line leak.

Results. The incidence of staple line leak was statistically significantly higher in Group I compared to Group II (5/40 vs. 0.46; χ² = 5.4, p = 0.021). This resulted in a statistically significant increase in blood loss (U = 706; p = 0.006), prolonged total operation time (U = 310; p = 0.001), and extended postoperative hospital stay (U = 245; p = 0.001) in Group I. The median time to healing of the leak was 32 [20; 59] days. No patient died.

Conclusions. Using the endostapler with purple cartridges with coating from Medtronic during laparoscopic sleeve gastrectomy significantly reduced postoperative leak rate and significantly decreased postoperative hospital stay.

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According to the World Health Organization, obesity has long become a global epidemic that affects people regardless of age, gender, race, or geographical location. Excess weight is a key factor in the development of insulin resistance and, subsequently, Type 2 diabetes. In addition, obesity associated with metabolic syndrome exacerbates the course of musculoskeletal, cardiovascular, respiratory, digestive, and reproductive system disorders [1].

Numerous meta-analyses and randomized clinical trials have demonstrated the advantages of bariatric surgery over conservative methods for treating obesity and its associated metabolic disorders [2,3].

Bariatric surgery has made a profound breakthrough in the last decade, and its popularity continues to grow with each passing year. This is evident from the increasing number of surgeries performed on every continent. For instance, in 2003, there were 146,000 such surgeries performed worldwide, but by 2016, this number had exceeded 685,000. Among the wide spectrum of bariatric procedures, laparoscopic sleeve gastrectomy (LSG) has confidently taken the lead as the most frequently performed bariatric operation globally [4]. A substantial body of literature attests to its effectiveness and safety in both the early and late postoperative periods, providing sustained and long-term weight loss and the mitigation of associated metabolic disorders, notably Type 2 diabetes [2,3].

Despite the positive outcomes in terms of reducing excess weight and managing obesity-related comorbidities, like all surgical procedures, it is not without its risks and complications. One of the most serious early complications in the perioperative period is staple line leak (SLL). Although the literature reports varying incidence rates of SLL ranging from 0.7% to 6.9%, the mortality in this group of patients can reach up to 60% [5].

Numerous publications in the literature discuss methods for preventing complications following LSG in the perioperative period. However, there is still no standardized approach to the optimal methodology for prevention.

**Aim**

The aim of the research is to evaluate the effect of using stapler with coating on preventing staple line leaks during laparoscopic sleeve gastrectomy in patients with morbid obesity.
Results

The characteristics of anthropometric parameters and comorbidities of the 91 patients included in this study are presented in Table 1.

The age of patients in the first group ranged from 20 to 64 (median 35 [26.5; 46.0] years), while in the second group, it ranged from 19 to 67 (median 44 years [35.5; 51.0] years). Patients in the first group were statistically significantly younger compared to patients in the second group (U = 692.5; p = 0.007).

The gender distribution in the first group was 20 males and 25 females, while in the second group, it was 29 males and 17 females. This distribution was the same in both study groups (χ² = 3.16, p = 0.08). The median body weight in the first group was 130 [124; 156] kg, which was slightly lower compared to the median body weight of patients in the second group, which was 153 [125.8; 174.5] kg (U = 777; p = 0.04). However, there was no statistically significant difference in BMI and excess body weight between the two groups. In the first group, the median BMI was 45.6 [41.1; 50.3] kg/m², and in the second group, it was 47.75 [42.90; 56.70] kg/m² (U = 792.5; p = 0.058). The median excess body weight in the first group was 68.0 [58.5; 84.5] kg, and in the second group, it was 73 [59.0; 92.6] kg (U = 796; p = 0.06).

Despite the fact that patients in the first group were younger than those in the second group, when analyzing the frequency distribution of patients based on the nature of comorbidities and physical status (ASA), no statistically significant differences were observed between the groups (p > 0.05). In all patients, the resection phase of the surgery was performed using endoscopic linear stapling devices from Medtronic. In the first group, cassettes without additional protection were used, while in the second group, cassettes with coating were used. There was no statistically significant difference in the number of cassettes used during the operation, as the average value in the first group.

Table 1: Characteristics of patients included in this research

<table>
<thead>
<tr>
<th>Indicator, units of measurement</th>
<th>M ± SD [min; max]</th>
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<tbody>
<tr>
<td>Age, years</td>
<td>40.6 ± 11.6 [19; 67]</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>49/42</td>
</tr>
<tr>
<td>Body weight, kg</td>
<td>146.1 ± 27.5 [100; 240]</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>48.4 ± 7.7 [37; 70]</td>
</tr>
<tr>
<td>Overweight, kg</td>
<td>78.6 ± 23.4 [43.0; 154.2]</td>
</tr>
<tr>
<td>Comorbidities, n (%)</td>
<td></td>
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<tr>
<td>Type 2 diabetes mellitus</td>
<td>36 (39.6 %)</td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>71 (78 %)</td>
</tr>
<tr>
<td>Non-alcoholic fatty liver disease</td>
<td>62 (68.1 %)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>73 (80.2 %)</td>
</tr>
<tr>
<td>Obstructive sleep apnea syndrome</td>
<td>66 (72.5 %)</td>
</tr>
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</table>

Stapler device from Medtronic with cartridges without additional reinforcement. In the second group, a similar procedure was performed, but the resection phase was carried out using the endostapler device with purple cartridges coated with polyglycolide from Medtronic. The stomach resection was performed on a 12 mm (36 Fr) calibrating probe, starting from a point 4 cm from the pylorus (the initial point of mobilization) to the angle of His. This was done to ensure a stomach tube width of 2 cm and a controlled 1 cm distance of the staple line from the esophagogastric junction. The resection phase was conducted with the condition of moderate lateral traction by an assistant along the greater curvature of the stomach strictly along the line of its mobilization.

In the first group, the staple line was peritonized on the calibration probe with a continuous serosa-to-serosa suture. In the second group, peritonealization was not performed. During the surgery, a leak test was conducted for each patient using a methylene blue solution through a nasogastric tube, and the operation was completed with abdominal cavity drainage.

Statistical data analysis was conducted using methods of descriptive and inferential statistics with the SPSS Statistics software, version 23, by IBM. Before beginning data analysis, all variables were checked for normal distribution using the Shapiro–Wilk test and for homogeneity of variances using the Levene’s test. In this study, descriptive statistical measures such as the mean (M) and standard deviation (SD) were used for normally distributed data, and the median (Me) and interquartile range [Q1; Q3] were used for non-normally distributed data. Statistically significant differences between relative indicators were assessed using the Pearson χ² (chi-squared) test with Yates’ correction and two-tailed Fisher’s exact test.

To assess statistically significant differences in the means of quantitative variables that follow a normal distribution, parametric methods were applied for independent groups, such as the Student’s t-test. For non-normally distributed data, the significance of differences in means between two independent groups was assessed using non-parametric methods, specifically the Mann–Whitney U test. Differences in results were considered statistically significant at p < 0.05, which provides a 95 % confidence level.
was 6.7 ± 0.9 pieces, and in the second group, it was 6.5 ± 0.7 pieces (t = 0.87; p = 0.38).

In all patients in the first group, the entire line of the stapler seam was additionally peritonealized with a continuous sero-serosal suture. In the second group, due to the use of the purple cartridges with coating, peritonealization was not performed in any case. This, in turn, led to a statistically significant reduction in the duration of the operation. The median duration of the operation in the first group was 135 [125; 140] minutes, while in the second group, it was 125 [105; 135] minutes (U = 310; p = 0.001).

Fig. 1. Intraoperative view of the methods of the sequential vertical resection of the stomach. A: The endostapler device from Medtronic with cartridges without additional reinforcement; B: The endostapler device with the purple cartridges with coating polyglycolide from Medtronic.

The SLL healed in all patients with conservative therapy, with the median healing time of 32 [20; 59] days, ranging from 10 to 83 days. There were no fatalities among the patients included in this study.

Discussion

Starting from 2014, LRYGB has become one of the most widely performed bariatric procedures. While in 2011, it accounted for only 17.8 % of all bariatric surgeries, by 2018, this figure had risen to 61.4 % [4].

However, like all surgical interventions, LRYGB is not without complications in the postoperative period. One of the life-threatening complications for patients is SLL. In the early stages of the technique’s development, studies reported SLL rates reaching 6.9 % [6].

Although the publication of the latest consensus summit, during which every stage of the operation and all key moments that could influence the development of SLL were analyzed, has led to a reduction in the SLL rate, recent data still indicate an average incidence of 1.35 % [7,8].

On modern forums, the etiology and pathogenesis of SLL remain topics for discussion. This is supported by numerous publications dedicated to this issue [9]. For example, T. Delko and colleagues, in their work, intraoperatively analyzed the microperfusion of the stomach wall during LRYGB. The authors found that microperfusion in the upper third of the stomach was significantly lower than in other regions [10]. The obtained results may explain the ischemic theory of SLL development, especially in cases of excessive devascularization of the stomach wall during mobilization at the gastroesophageal junction.

Among other factors that can influence the development of SLL, there are mechanical factors directly related to the technical execution of LRYGB. One of the key elements in the successful execution of LRYGB is the choice of cartridges with an optimal staple height. It has already been proven that the thickness of
the stomach wall differs in various sections and can also depend on gender and BMI [9]. This is evidenced by numerous studies that have focused on the role of stomach wall thickness in the development of SLL. For instance, in their research, C. Boeker and colleagues found that stomach wall thickness can influence the occurrence of SLL [11]. Therefore, the modern medical industry has developed endoscopic staplers with cartridges of varying staple heights. It is objectively challenging to determine stomach wall thickness during surgery, and it can only be reliably assessed using endoscopic sonographic examination. However, the choice of cartridge before stapling typically relies on the surgeon’s subjective assessment of stomach wall thickness and their experience.

During LRYGB, green cartridges (staple depth of 4.8 mm) are typically used for the first two to three firings, followed by blue cartridges (3.5 mm). For example, in their study, Q. Sun and colleagues analyzed the treatment results of patients after laparoscopic low anterior resection of the rectum, depending on the type of cartridges used to form the anastomosis. The authors found that the use of stapler with coating statistically significantly reduced the incidence of colorectal anastomotic insufficiency (p < 0.05) [12].

Nevertheless, despite the optimal selection of cartridges for stapling during LRYGB, most surgeons tend to use additional reinforcement of the staple line to prevent insufficiency and bleeding. According to a consensus statement published in 2021, which was based on a survey of leading bariatric surgeons worldwide, the majority of respondents prefer additional reinforcement of the staple line. However, none of the currently available reinforcement techniques have sufficient evidence regarding the prevention of SLL [13].

At the same time, there are publications in the literature in which authors, through their own standardized experience in performing LRYGB and adhering to a unified protocol for postoperative patient management, have managed to minimize complications without additional reinforcement of the staple line. Even by implementing early enteral nutrition and avoiding nasogastric decompression of the gastric tube in patients after LRYGB, it is possible to reduce the incidence of SLL [14,15]. Similar results were obtained by W. Lynn and colleagues, who published their experience based on the treatment of 303 patients. By using their own tactical and technical aspects of the surgery and adhering to a patient management protocol, they successfully avoided SLL, and none of the patients experienced this complication [16].

Common methods of SLL prevention include peritonization of the staple line, treatment of the staple line with adhesive mixtures (based on fibrin and cyanoacrylate), and the use of protective plates made of absorbable and non-absorbable materials [9].

One of the most common methods of protection is peritonization of the staple line. For example, G. Özgen and colleagues published the results of this prevention method in 1008 patients undergoing LRYGB. SLL occurred in 1 patient, which amounted to 0.1 %. However, it is noteworthy that there was a relatively high rate of gastric tube strictures in 17 (1.7 %) patients [17].

In contrast, H. Wang and colleagues obtained different results. They published a meta-analysis examining the utility of peritonization of the staple line in LRYGB. This meta-analysis included 7 randomized clinical trials involving 845 patients. The authors concluded that peritonization of the staple line increases the duration of the surgical procedure and does not affect the risk of SLL (RR: 0.650, 95 % CI: 0.257–1.644, p = 0.363) [18].

Similar results were obtained in our study, where the duration of the operation in the group of patients who underwent peritonization was significantly longer (U = 310; p = 0.001).

Initially, adhesive mixtures were used in herniology to fix mesh prostheses. However, over time, they began to be increasingly used for preventing SLL in gastrointestinal surgery, including bariatric procedures. For example, G. Martines and colleagues published the results of comparing the use of cyanoacrylate-based glue to protect the staple line in LRYGB with a group of patients who did not receive additional protection for the staple line. In the first group (treated with glue), no cases of SLL were observed, while in the second group, insufficiency occurred in 2 (3.6 %) patients. However, according to the results of this study, this difference did not reach statistical significance [19]. Similar results were obtained by D. E. Bellanger and colleagues, who published the outcomes of treating 529 patients after LRYGB. Due to the use of fibrin glue to seal the staple line, no cases of SLL were reported [20].

At the same time, S. Carandina and colleagues came to a slightly different conclusion based on their own randomized clinical trial. This study included 600 patients who were divided according to the method of additional protection for the staple line (150 patients in each group). In the first group, no additional protection was used; in the second group, fibrin glue was used; in the third group, peritoneal closure with MonocrylTM suture was performed; and in the fourth group, peritoneal closure with V-LocTM suture was performed. Cases of SLL were observed in all groups: in the first group (no protection) – in 3 (2 %) patients, in the second group (glue) – in 4 (2.6 %) patients, in the third group (MonocrylTM) – in 3 (2 %) patients, and in the fourth group (V-LocTM) – in 4 (2.6 %) patients. This difference did not reach statistical significance (p = 0.96). Similarly, the rates of bleeding and stenosis did not reach statistical significance (p > 0.05) [21].

In order to provide additional protection to the staple line, the medical industry began developing coatings (membranes) for cartridges that were intended to prevent complications in the postoperative period. However, not all membranes have given the expected satisfactory results. For instance, M. Gagner and colleagues conducted a systematic review based on 148 studies, including 40,653 patients, to analyze the effectiveness of various methods for protecting the staple line during LRYGB. The first group (no additional protection) included 16,632 patients, the second group (peritoneal closure) included 18,314 patients, the third group (bovine pericardial coverage) included 1,244 patients, the fourth group (glue) included 363 patients, and the fifth group (absorbable polymer membrane) included 4,100 patients. The rate of SLL was highest in the third group (2.7 %), where bovine pericardial coverage was used. The lowest rate (0.7 %) was observed when using the absorbable polymer membrane [22].
Taking into account our own experience and numerous publications, additional protection of the staple line allows for a reduction in the rate of SLL. In our opinion, the most effective method for preventing SLL is the use of purple cartridges with coating. In our study, the use of these cartridges prevented the development of SLL in all patients in the second group.

Conclusions

1. Laparoscopic sleeve gastrectomy has proven to be a safe and effective primary weight loss operation. Still, complications remain the primary concern after this intervention.

2. Staple line leak is the most dreaded postoperative complication following laparoscopic sleeve gastrectomy.

3. The use of cartridges with coating statistically significantly prevents the development of staple line leak during laparoscopic sleeve gastrectomy and reduces the length of hospital stay for patients.

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